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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/531,540 | 04/15/2005 | Stanka Perc | 4061-27PUS | 1415 |
| 27799 | 7590 | 03/12/2009 | EXAMINER | |
| COHEN, PONTANI, LIEBERMAN & PAVANE LLP | | | JEAN-LOUIS, SAMIRA JM | |
| 551 FIFTH AVENUE | | | | |
| SUITE 1210 | | | ART UNIT | PAPER NUMBER |
| NEW YORK, NY 10176 | | | 1617 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/12/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|---|------------------------|---------------------|
| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) |
| | 10/531,540 | PERC ET AL. |
| | Examiner | Art Unit |
| | SAMIRA JEAN-LOUIS | 1617 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) The period for reply expires _____ months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 - (a) They raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) They raise the issue of new matter (see NOTE below);
 - (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. Applicant's reply has overcome the following rejection(s): _____.
6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Applicant's argument that Morris does not teach an uncoated olanzapine has been fully considered but is not found persuasive. While Morris teaches the use of coated olazanpine in the blended mixture, Morris also suggested that preferably the olanzapine is coated thereby suggesting to one of ordinary skill in the art that a non-coated olanzapine can also be envisioned since the teachings of Morris are preferred embodiments. Additionally, Morris et al. teach that uncoated tablets stored at ambient temperatures in amber, high density polyethylene glycol do not show signs of discoloration further supporting the notion as to why one of ordinary skill in the art can envision a non-coated tablet. Consequently, the Examiner asserts that one of ordinary skill in the art would have found it obvious to at least try the formulation of Morris using uncoated olanzapine if the desire is for an olanzapine that is rapidly consumed thereby avoiding discoloration problems disclosed in the prior art. As for applicant's arguments that the olanzapine is discolored within 5 days after exposure to air and thus one would not be able to ascertain the discoloration period. Such arguments are again not persuasive as various packaging methods are well known in the art so that the discoloration period could indeed be prolonged and predicted. Consequently, Morris does indeed render obvious applicant's invention.

Applicant's arguments with respect to the search report in the WIPO document has again been fully considered but is not found persuasive. While the search report provides information on relevant materials and addresses novelty issues, the Examiner again reiterates the fact that U.S. practice differs from that of WIPO and the EPO. Moreover, the search report does not unequivocally teach allowable subject matter but rather points out claims that appear to satisfy the PCT Article 33 criteria. Thus, the Examiner contends that in view of a lack of novelty and/or inventive step, U.S. practices dictate rejection of such claims.

The Examiner therefore asserts that the rejections of record were indeed proper and are therefore maintained. Moreover, given that newly added claims 35-51 were previously dependent on cancelled claim 18, the Examiner contends that the scope of the invention for the dependent claims have also been changed. Thus, such amendment to the claims will not be entered.